

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 13 Sheets

Complete if Known

Application Number	10/021,403
Filing Date	December 12, 2001
First Named Inventor	Schwartz, Robert J
Group Art Unit	1632
Examiner Name	Joanne Hama
Attorney Docket Number	AVSI-0009 (108328.00031)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
SH	1.	5,847,066		Coy et al.	Dec. 8, 1998	Entire Patent
	2.	5,846,936		Felix et al.	Dec. 8, 1998	Entire Patent
	3.	5,792,747		Schally et al.	Aug. 11, 1998	Entire Patent
	4.	5,776,901		Bowers et al.	Jul. 7, 1998	Entire Patent
	5.	5,756,264		Schwartz et al.	26-May-98	Entire Patent
	6.	5,696,089		Felix et al.	Dec. 9, 1997	Entire Patent
	7.	5,486,505		Bowers et al.	Jan. 23, 1996	Entire Patent
	8.	5,292,721		Boyd et al.	Mar. 8, 1994	Entire Patent
	9.	5,137,872		Seely et al.	Aug. 11, 1992	Entire Patent
	10.	5,134,210		Boyd et al.	Jul. 28, 1992	Entire Patent
SH	11.	5,084,442		Felix et al.	Jan. 28, 1992	Entire Patent
	12.	5,061,690		Kann et al.	Oct. 29, 1991	Entire Patent
	13.	5,036,045		Thomer.	Jul. 30, 1991	Entire Patent
	14.	5,023,322		Kovacs et al.	Jun. 11, 1991	Entire Patent
	15.	4,839,344		Bowers et al.	Jun. 13, 1989	Entire Patent
	16.	4,410,512		Bowers et al.	Oct. 18, 1983	Entire Patent

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

Examiner Signature

Joanne Hama

Date Considered

8/1/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1632	
			Examiner Name	Joanne Hama	
			Attorney Docket Number	AVSI-0009 (108328.00031)	
Sheet	2	of	13 Sheets		

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	17.	RE33,699		Drengler.	Sep. 24, 1991	Entire Patent
	18.	4,833,166		Grosvenor et al.	23-May-89	Entire Patent
	19.	4,228,158		Momany et al.	Oct. 14, 1980	Entire Patent
	20.	4,228,156		Momany et al.	Oct. 14, 1980	Entire Patent
	21.	4,226,857		Momany et al.	Oct. 7, 1980	Entire Patent
	22.	4,224,316		Momany et al.	Sep. 23, 1980	Entire Patent
	23.	4,223,021		Momany et al.	Sep. 16, 1980	Entire Patent
	24.	4,223,020		Momany et al.	Sep. 16, 1980	Entire Patent
	25.	4,223,019		Momany et al.	Sep. 16, 1980	Entire Patent

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

Examiner Signature Joanne Hama	Date Considered 7/27/05
---------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	3	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	26.	AIHARA, H. & Miyazaki, J. Nat. Biotechnol. 16, 867-870 (1998).	
	27.	ALBANESE, A. and R. Stanhope. 1997. GH treatment induces sustained catch-up growth in children with intrauterine growth retardation: 7-year results. Horm. Res. 48:173-177.	
gh	28.	ALLEN, D. B., A. C. Rundle, D. A. Graves, and S. L. Blethen. 1997. Risk of leukemia in children treated with human growth hormone: review and reanalysis. J. Pediatr. 131:S32-S36.	
	29.	ARAMBURO, C., Luna, M., Carranza, M., Reyes, M., Martinez-Coria, H., Scanes, C. G. (2000) Growth hormone size variants: changes in the pituitary during development of the chicken. Proc. Soc. Exp. Biol. Med. 223, 67-74.	
	30.	ARGENTE, J., Pozo, J., Chowen, J. A. (1996) The growth hormone axis: control and effects. Hormone Research 45 Suppl 1, 9-11.	
	31.	ASA, S. L., Kovacs, K., Stefanescu, L., Horvath, E., Billestrup, N., Gonzalez-Manchon, C., Vale, W. (1992) Pituitary adenomas in mice transgenic for growth hormone-releasing hormone. Endocrinology 131, 2083-2089.	
	32.	AZCONA, C., A. Albanese, P. Bareille, and R. Stanhope. 1998. Growth hormone treatment in growth hormone-sufficient and -insufficient children with intrauterine growth retardation/Russell-Silver syndrome. Horm. Res. 50:22-27.	
	33.	BARR, E., Leiden, J. M. (1991) Systemic delivery of recombinant proteins by genetically modified myoblasts. Science 254, 1507-1509.	
	34.	BARTKE, A. 1998. Growth hormone and aging. Endocrine 8:103-108.	

Examiner Signature	Joanne Hama	Date Considered	7/27/05
--------------------	-------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	4	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	35.	BENFIELD, M. R. and E. C. Kohaut. 1997. Growth hormone is safe in children after renal transplantation. J. Pediatr. 131:S28-S31.	
	36.	BERCU, B. B., R. F. Walker. 1997. Growth hormone secretagogues in children with altered growth. Acta Paediatrica 86:102-106.	
	37.	BERGSMA, D. J., Grichnik, S. M., Gossett, L. M. & Schwartz, R. J. Mol. Cell. Biol. 6, 2462-2475 (1986).	
	38.	BETTAN, M., Emmanuel, F., Darteil, R., Caillaud, J. M., Soubrier, F., Delaere, P., Branelec, D., Mahfoudi, A., Duverger, N., Scherman, D. (2000) High-level protein secretion into blood circulation after electric pulse-mediated gene transfer into skeletal muscle. Mol. Ther. 2, 204-210.	
	39.	BILLESTRUP, N., Gonzalez-Manchon, C., Potter, E., Vale, W. (1990) Inhibition of somatotroph growth and growth hormone biosynthesis by activin in vitro. Mol. Endocrinol. 4, 356-362.	
	40.	BLETHEN, S. L. and A. C. Rundle. 1996. Slipped capital femoral epiphysis in children treated with growth hormone. A summary of the National Cooperative Growth Study experience. Horm. Res. 46:113-116.	
	41.	BOWERS, C. Y. 1998. Growth hormone-releasing peptide (GHRP). Cell Mol Life Sci. 54(12):1316-29.	
	42.	CAMPBELL, R. M., Y. Lee, J. Rivier, E. P. Heimer, A. M. Felix, and T. F. Mowles. 1991. GRF analogs and fragments: correlation between receptor binding, activity and structure. Peptides 12:569-574.	
	43.	CHUNG, C. S., Etherton, T. D., Wiggins, J. P. (1985) Stimulation of swine growth by porcine growth hormone. J. Anim Sci. 60, 118-130.	

Examiner Signature	Joanne Hama	Date Considered	7/27/05
-----------------------	-------------	--------------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	5	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	44.	CORPAS, E., S. M. Harman, and M. R. Blackman. 1993. Human growth hormone and human aging. Endocrine Reviews 14:20-39.	
	45.	CORPAS, E., S. M. Harman, M. A. Pineyro, R. Roberson, and M. R. Blackman. 1993. Continuous subcutaneous infusions of growth hormone (GH) releasing hormone 1-44 for 14 days increase GH and insulin-like growth factor-I levels in old men. Journal of Clinical Endocrinology & Metabolism 76:134-138.	
	46.	DAHLER, A., Wade, R. P., Muscat, G. E., Waters, M. J. (1994) Expression vectors encoding human growth hormone (hGH) controlled by human muscle-specific promoters: prospects for regulated production of hGH delivered by myoblast transfer or intravenous injection. Gene 145, 305-310.	
	47.	DAVIS, H. L., Whalen, R. G. & Demeneix, B. A. Hum. Gene Ther. 4, 151-159 (1993).	
	48.	D'COSTA, A. P., R. L. Ingram, J. E. Lenham, and W. E. Sonntag. 1993. The regulation and mechanisms of action of growth hormone and insulin-like growth factor 1 during normal aging. J. Reprod. Fert.-Supp. 46:87-98.	
	49.	DHAWAN, J., Pan, L. C., Pavlath, G. K., Travis, M. A., Lanctot, A. M., Blau, H. M. (1991) Systemic delivery of human growth hormone by injection of genetically engineered myoblasts. Science 254, 1509-1512.	
gh	50.	DIEGUEZ C, Casanueva F F. 2000. Ghrelin: a step forward in the understanding of somatotroph cell function and growth regulation. Eur J Endocrinol. 142(5):413-7.	
	51.	DRAGHIA-AKLI, R., Li, X. G., Schwartz, R. J., et al. Nat. Biotechnol. 15, 1285-1289 (1997).	
	52.	DRAGHIA-AKLI, R. Fiorotto M L, Hill L A, Malone P B, Deaver D R, Schwartz R J Nat Biotechnol, 17(12), 1179-83 (1999).	

Examiner Signature	Joan [Signature]	Date Considered	7/27/05
--------------------	------------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	6	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	53.	DUBREUIL, P., Petitclerc, D., Pelletier, G., Gaudreau, P., Farmer, C., Mowles, T F, Brazeau, P. (1990) Effect of dose and frequency of administration of a potent analog of human growth hormone-releasing factor on hormone secretion and growth in pigs. Journal of Animal Science 68, 1254-1268.	
	54.	EICHER, E. M. and W. G. Beamer. 1976. Inherited ateliotic dwarfism in mice. Characteristics of the mutation, little, on chromosome 6. J. Hered. 67:87-91.	
	55.	ERLING, A. 1999. Methodological considerations in the assessment of health-related quality of life in children. Acta Paediatrica Scand. --Supp. 428:106-107. 0803-5326.	
	56.	ESCH, F. S., P. Bohlen, N. C. Ling, P. E. Brazeau, W. B. Wehrenberg, M. O. Thorner, M. J. Cronin, and R. Guillemin. 1982. Characterization of a 40 residue peptide from a human pancreatic tumor with growth hormone releasing activity. Biochemical & Biophysical Research Communications 109:152-158.	
	57.	ETHERTON, T. D., Wiggins, J. P., Chung, C. S., Evock, C. M., Rebhun, J. F., Walton, P. E. (1986) Stimulation of pig growth performance by porcine growth hormone and growth hormone-releasing factor. Journal of Animal Science 63, 1389-1399.	
	58.	ETIENNE, M., Bonneau, M., Kann, G., Deletang, F. (1992) Effects of administration of growth hormone-releasing factor to sows during late gestation on growth hormone secretion, reproductive traits, and performance of progeny from birth to 100 kilograms live weight. Journal of Animal Science 70, 2212-2220.	
	59.	EVERETT, R. S., Gerrard, D. E., Grant, A. L. (2000) Factors affecting production of luciferase and epitope-tagged IGF-I in porcine muscle after DNA injection. J Endocrinol. 166, 255-263.	
✓	60.	FARMER, C., Petitclerc, D., Pelletier, G., Brazeau, P. (1992) Lactation performance of sows injected with growth hormone-releasing factor during gestation and/or lactation. Journal of Animal Science 70, 2636-2642.	

Examiner Signature	<i>Joanne Hama</i>	Date Considered	7/27/05
--------------------	--------------------	-----------------	---------

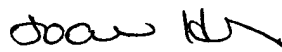
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	7	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	61.	FAGLIA, G., Arosio, M., Bazzoni, N. (1992) Ectopic acromegaly. [Review]. Endocrinology & Metabolism Clinics of North America 21, 575-595.	
	62.	FROHMAN, M. A., T. R. Downs, P. Chomczynski, and L. A. Frohman. 1989. Cloning and characterization of mouse growth hormone-releasing hormone (GRH) complementary DNA: increased GRH messenger RNA levels in the growth hormone-deficient lit/lit mouse. Mol. Endocrinol. 3:1529-1536.	
	63.	FROHMAN, L. A., J. L. Thominet, C. B. Webb, M. L. Vance, H. Uderman, J. Rivier, W. Vale, and M. O. Thorner. 1984. Metabolic clearance and plasma disappearance rates of human pancreatic tumor growth hormone releasing factor in man. J. Clin. Invest. 73:1304-1311.	
	64.	GEFFNER, M. (1997) Effects of growth hormone and insulin-like growth factor I. Acta Paediatr. Suppl 423, 76-79.	
	65.	GESUNDHEIT, N. and J. K. Alexander. 1995. Endocrine Therapy with Recombinant Hormones and Growth Factors. In Molecular Endocrinology: Basic Concepts and Clinical Correlations. B. D. Weintraub, editor. Raven Press, Ltd., New York. 491-507.	
	66.	GOPINATH, R., Etherton, T. D. (1989) Effects of porcine growth hormone on glucose metabolism of pigs: I. Acute and chronic effects on plasma glucose and insulin status. J. Anim Sci. 67, 682-688.	
	67.	HATAYA, Y., Akamizu, T., Takaya, K., Kanamoto, N., Ariyasu, H., Saijo, M., Moriyama, K., Shimatsu, A., Kojima, M., Kangawa, K., Nakao, K. (2001) A low dose of ghrelin stimulates growth hormone (GH) release synergistically with GH-releasing hormone in humans. J. Clin. Endocrinol. Metab 86, 4552.	
	68.	HATTORI, N., Saito, T., Yagyu, T., Jiang, B. H., Kitagawa, K., Inagaki, C. (2001) GH, GH receptor, GH secretagogue receptor, and ghrelin expression in human T cells, B cells, and neutrophils. J. Clin. Endocrinol. Metab 86, 4284-4291.	
↓	69.	HEPTULLA, R. A., S. D. Boulware, S. Caprio, D. Silver, R. S. Sherwin, and W. V. Tamborlane. 1997. Decreased insulin sensitivity and compensatory hyperinsulinemia after hormone treatment in children with short stature. J. Clin. Endocrinol. Metab. 82:3234-3238.	

Examiner Signature		Date Considered	7/27/05
--------------------	-------------------------------------------------------------------------------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1448A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1684 1632	
			Examiner Name	Joanne Hama	
Sheet	8	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gt	70.	HORVATH, T. L., Diano, S., Sotonyi, P., Heiman, M., Tschop, M. (2001) Minireview: ghrelin and the regulation of energy balance-a hypothalamic perspective. Endocrinology 142, 4163-4169.	
	71.	HOWARD, A. D., Feighner, S. D., Cully, D. F. Arena, J P., Liberator, P. A., Rosenblum, C. I., Hamelin, M., Hreniuk, D. L., Palyha, O. C., Anderson, J., Parese, P. S., Diaz, C., Chou, M., Liu, K. K., McKee, K. K., Pong, S. S., Chaung, L., Elbrecht, A., Dashkevich, M., Heavens, R., Rigby, M., Sirinathsinghji, D., Dean, D. C., Melillo, D. G., Patchett, A. A., Nargund, R., Griffin, P. R., DeMartino, J. A., Gupta, S. K., Schaeffer, J. M., Smith R. G., Van der Ploeg, L. H. T. (1996) Receptor in pituitary and hypothalamus that functions growth hormone release. Science 273: 974-977.	
	72.	IRANMANESH, A., G. Lizarralde, and J. D. Veldhuis. 1991. Age and relative adiposity are specific negative determinants of the frequency and amplitude of growth hormone (GH) secretory bursts and the half-life of endogenous GH in healthy men. Journal of Clinical Endocrinology & Metabolism 73:1081-1088.	
	73.	JACOBS, P. A., P. R. Betts, A. E. Cockwell, J. A. Crolla, M. J. Mackenzie, D. O. Robinson, and S. A. Youings. 1990. A cytogenetic and molecular reappraisal of a series of patients with Turner's syndrome. Ann. Hum. Genet. 54:209-223.	
	74.	JAFFE, H. A., C. Danel, G. Longenecker, M. Metzger, Y. Setoguchi, M. A. Rosenfeld, T. W. Gant, S. S. Thorgeirsson, L. D. Stratford-Perricaudet, M. Perricaudet, A. Pavirani, J. -P. Lecocq and R. G. Crystal. 1992. Adenovirus-mediated in vivo gene transfer and expression in normal rat liver. Nat Genet 1(5):372-8.	
	75.	KEY, L. L. J. and A. J. Gross. 1996. Response to growth hormone in children with chondrodysplasia. J. Pediatr. 128:S14-S17.	
	76.	KLINDT, J., Yen, J. T., Buonomo, F. C., Roberts, A. J., Wise, T. (1998) Growth, body composition, and endocrine responses to chronic administration of insulin-like growth factor I and(or) porcine growth hormone in pigs. J. Anim Sci. 76, 2368-2381.	
	77.	KOJIMA M, Hosoda H, Date Y, Nakazato M, Matsuo H, Kangawa K. 1999. Ghrelin is a growth-hormone-releasing acylated peptide from stomach. Nature 402(6762):656-60.	
	78.	KUBIAK, T. M., C. R. Kelly, and F. Krabill. 1989. In vitro metabolic degradation of a bovine growth hormone-releasing factor analog Leu27-bGRF(1-29)NH2 in bovine and porcine plasma. Correlation with plasma dipeptidylpeptidase activity. Drug Metabolism & Disposition 17:393-397.	

Examiner Signature	<i>Joanne Hama</i>	Date Considered	7/27/05
--------------------	--------------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete If Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1684 1632	
			Examiner Name	Joanne Hama	
Sheet	9	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
gh	79.	LI, X., Eastman, E. M., Schwartz, R. J., & Draghia-Akli, R. Nat. Biotechnol. 17, 3, 241-245 (1999).	
↓	80.	LOPEZ-CALDERON, A., Soto, L., Villanua, M. A., Vidarte, L., Martin, A. I. (1999) The effect of cyclosporine administration on growth hormone release and serum concentrations of insulin-like growth factor-I in male rats. Life Sci. 64, 1473-1483.	
	81.	MARTIN, R. A., D. L. Cleary, D. M. Guido, H. A. Zurcher-Neely, and T. M. Kubiak. 1993. Dipeptidyl peptidase IV (DPP-IV) from pig kidney cleaves analogs of bovine growth hormone-releasing factor (bGRF) modified at position 2 with Ser, Thr or Val. Extended DPP-IV substrate specificity? Biochimica et Biophysica Acta 1164:252-260.	
	82.	MELMED, S. (1991) Extrapituitary Acromegaly. [Review]. Endocrinology & Metabolism Clinics of North America 20, 507-518.	
↓	83.	MILLER, K. F., Bolt, D. J., Pursel, V. G., Hammer, R. E., Pinkert, C. A., Palmiter, R. D., Brinster, R. L. (1989) Expression of human or bovine growth hormone gene with a mouse metallothionein-1 promoter in transgenic swine alters the secretion of porcine growth hormone and insulin-like growth factor-I. J. Endocrinol. 120, 481-488.	
gh	84.	MIR, L. M., Bureau, M. F., Gehl, J., Rangara, R., Rouy, D., Caillaud, J. M., Delaere, P., Branellec, D., Schwartz, B., Scherman, D. (1999) High-efficiency gene transfer into skeletal muscle mediated by electric pulses. Proc. Natl. Acad. Sci. U.S.A 96, 4262-4267.	
	85.	MONTI, L. D., P. Brambilla, A. Caumo, F. Magni, S. Omati, G. Nizzoli, B. di Natale, M. Galli-Kienle, C. Cobelli, G. Chiumello, and G. Pozza. 1997. Glucose turnover and insulin clearance after growth hormone treatment in girls with Turner's syndrome. Metabolism 46:1482-1488.	
	86.	MOREL, G., Gallego, R., Boulanger, L., Pintos, E., Garcia-Caballero, T., Gaudreau, P. (1999) Restricted presence of the growth hormone-releasing hormone receptor to somatotropes in rat and human pituitaries. Neuroendocrinology 70, 128-136.	
↓	87.	MURAMATSU, T., Nakamura, A. & Park, H. M. Int. J. Mol. Med. 1, 55-62 (1998).	

Examiner Signature	Joanne Hama	Date Considered	7/27/05
--------------------	-------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1654 1632	
			Examiner Name	Joanne Hama	
Sheet	10	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
9H	88.	MURRAY, R. A., Maheshwari, H. G., Russell, E. J., Baumann, G. (2000) Pituitary hypoplasia in patients with a mutation in the growth hormone-releasing hormone receptor gene. <i>AJNR Am. J Neuroradiol.</i> 21, 685-689.	
	89.	MURRAY, R. D., Shalet, S. M. (2000) Growth hormone: current and future therapeutic applications. <i>Expert. Opin. Pharmacother.</i> 1, 975-990.	
	90.	PARKS, J. S., R. W. Pfaffle, M. R. Brown, H. Abdul-Latif, and L. R. Meacham. 1995. Growth Hormone Deficiency. In <i>Molecular Endocrinology: Basic Concepts and Clinical Correlations</i> . B. D. Weintraub, editor. Raven Press, Ltd., New York. 473-490.	
	91.	PONG, S. -S., Chaung, L. -Y. P., Dean, D. C., Nargund, R. P., Patchett, A. A. and Smith, R. G. (1996). Identification of a new G-protein-linked receptor for growth hormone secretagogues. <i>Molecular Endocrinology</i> 10: 57-61.	
	92.	PURSEL, V. G., Hammer, R. E., Bolt, D. J., Palmiter, R. D., Brinster, R. L. (1990) Integration, expression and germ-line transmission of growth-related genes in pigs. [Review]. <i>Journal of Reproduction & Fertility--Supplement</i> 41, 77-87.	
	93.	PURSEL, V. G., Bolt, D. J., Miller, K. F., Pinkert, C. A., Hammer, R. E., Palmiter, R. D., Brinster, R. L. (1990) Expression and performance in transgenic pigs. <i>J. Reprod. Fertil. Suppl</i> 40:235-45, 235-245.	
↓	94.	RAWLINGS, S. R., Piuz, I., Schlegel, W., Bockaert, J., Journot, L. (1995) Differential expression of pituitary adenylate cyclase-activating polypeptide/vasoactive intestinal polypeptide receptor subtypes in clonal pituitary somatotrophs and gonadotrophs. <i>Endocrinology</i> 136, 2088-2098.	
	95.		

Examiner Signature	<i>Joanne Hama</i>	Date Considered	7/27/05
--------------------	--------------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403
			Filing Date	December 12, 2001
			First Named Inventor	Schwartz, Robert J
			Group Art Unit	1654 1632
			Examiner Name	Joanne Hama
Sheet 11 of 13 Sheets	Attorney Docket Number		AVSI-0009 (108328.00031)	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
GH	96.	ROSENFELD, M. A., K Yoshimura, L. E. Stier, B. C. Trapnell, L. D. Stratford-Perricaudet, M. Perricaudet, W. Dalemans, S. Jallat, A. Mercenier, A. Pavirani, J. P. Lecocq, W. B. Guggino, R. G. Crystal. 1991. In vivo transfer of the human cystic fibrosis gene to the respiratory epithelium. Clinical Research 39 (2), 311A.	
	97.	ROSENFELD, M. A., W Siegfried, K Yoshimura, K Yoneyama, M Fukayama, L E Stier, P K Paakko, P Gilardi, L D Stratford-Perricaudet, M Perricaudet, S. Jallat, A. Pavirani, J. -P. Lecocq, and R. G. Crystal. 1991. Adenovirus-mediated transfer of a recombinant alpha 1-antitrypsin gene to the lung epithelium in vivo. Science 252(5004):431-4.	
GH	98.	SANO, T., Asa, S. L., Kovacs, K. (1988) Growth hormone-releasing hormone-producing tumors: clinical, biochemical, and morphological manifestations. Endocr. Rev. 9, 357-373.	
	99.	SAVAGE, M. O., R. M. Beattie, C. Camacho-Hubner, J. A. Walker-Smith, and I. R. Sanderson. 1999. Growth in Crohn's disease. Acta Paediatrica Scand--Supp. 428:89-92.	
	100.	SCANLON, M. F., B. G. Issa, and C. Dieguez. 1996. Regulation of Growth Hormone Secretion. Hormone Research 46:149-154.	
	101.	SHALET, S. M., B. M. Brennan, and R. E. Reddingius. 1997. Growth hormone therapy and malignancy. Horm. Res. 48 Suppl 4:29-32:29-32.	
	102.	SKUSE, D. H., K. Elgar, and E. Morris. 1999. Quality of life in Turner syndrome is related to chromosomal constitution: implication for genetic counseling and management. Acta Paediatrica Scand--Supp. 428:110-113.	
	103.	SMITH, V. G., Leman, A. D., Seaman, W. J., VanRavenswaay, F. (1991) Pig weaning weight and changes in hematology and blood chemistry of sows injected with recombinant porcine somatotropin during lactation. J. Anim Sci. 69, 3501-3510.	
↓	104.	SMITH, R. G., Van der Ploeg, L. H. T., Cheng, K., Hickey, G. J., Wyvratt, Jr., M. J., Fisher, M. H., Nargund, R. P., Patchett, A. A. (1997) Peptidomimetic regulation of growth hormone (GH) secretion. Endocrine Reviews 18: 621-645.	

Examiner Signature	Joanne Hama	Date Considered	7/27/05
--------------------	-------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1634 1632	
			Examiner Name	Joanne Hama	
Sheet	12	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
97H	105.	SOHMIYA, M., K. Ishikawa, and Y. Kato. 1998. Stimulation of erythropoietin secretion by continuous subcutaneous infusion of recombinant human GH in anemic patients with chronic renal failure. Eur. J. Endocrinol. 138:302-306.	
	106.	SU, C. M., L. R. Jensen, E. P. Heimer, A. M. Felix, Y. C. Pan, and T. F. Mowles. 1991. In vitro stability of growth hormone releasing factor (GRF) analogs in porcine plasma. Hormone & Metabolic Research 23:15-21.	
	107.	TANAKA, H., T. Kubo, T. Yamate, T. Ono, S. Kanzaki, and Y. Seino. 1998. Effect of growth hormone therapy in children with achondroplasia: growth pattern, hypothalamic-pituitary function, and genotype. Eur. J. Endocrinol. 138:275-280.	
	108.	TANNER, J. W., Davis, S. K., McArthur, N. H., French, J. T. & Welsh, T. H., Jr. J. Endocrinol. 125, 109-115 (1990).	
	109.	THORNER, M. O., Hartman, M. L., Vance, M. L., Pezzoli, S. S., Ampleford, E. J. (1995) Neuroendocrine regulation of growth hormone secretion. [Review]. Neuroscience & Biobehavioral Reviews 19, 465-468.	
	110.	THORNER, M. O., L. A. Frohman, D. A. Leong, J. Thominet, T. Downs, P. Hellmann, J. Chitwood, J. M. Vaughan, and W. Vale. 1984. Extrahypothalamic growth-hormone-releasing factor (GRF) secretion is a rare cause of acromegaly: plasma GRF levels in 177 acromegalic patients. Journal of Clinical Endocrinology & Metabolism 59:846-849.	
	111.	TOMIC, M., Zivadinovic, D., Van Goor, F., Yuan, D., Koshimizu, T., Stojilkovic, S. S. (1999) Expression of Ca(2+)-mobilizing endothelin(A) receptors and their role in the control of Ca(2+) influx and growth hormone secretion in pituitary somatotrophs. J Neurosci. 19, 7721-7731.	
	112.	TRIPATHY, S. K., Svensson, E. C., Black, H. B., et al. Proc. Natl. Acad. Sci. USA 93, 10876-10880 (1996).	
✓	113.	VELDHUIS, J. D. (1998) Neuroendocrine control of pulsatile growth hormone release in the human: relationship with gender. Growth Horm. IGF. Res. 8 Suppl B, 49-59.	

Examiner Signature	<i>Joanne Hama</i>	Date Considered	7/27/05
--------------------	--------------------	-----------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/021,403	
			Filing Date	December 12, 2001	
			First Named Inventor	Schwartz, Robert J	
			Group Art Unit	1634 1632	
			Examiner Name	Joanne Hama	
Sheet	13	of	13 Sheets	Attorney Docket Number	AVSI-0009 (108328.00031)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
GH	114.	WALTER, R., W. H. Simmons, and T. Yoshimoto. 1980. Proline specific endo- and exopeptidases. Mol. Cell Biochem. 30:111-127.	
↓	115.	WATKINS, S. L. 1996. Bone disease in patients receiving growth hormone. Kidney Int. Suppl. 53:S126-7:S126-S127.	
↓	116.	WOLFF, J. A., Ludtke, J. J., Acsadi, G., Williams, P., Jani, A. (1992) Long-term persistence of plasmid DNA and foreign gene expression in mouse muscle. Human Molecular Genetics 1, 363-369	

Examiner Signature	Joanne Hama	Date Considered	7/27/05
-----------------------	-------------	--------------------	---------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case.

Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.